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10/533,013	04/28/2005	Koushi Nakano	Saeg153.002APC	1676

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,013	NAKANO ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *13-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/28/2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-25 are pending. Claims 13-25 were previously withdrawn as non-elected subject matter. Claim 5 is currently amended by Applicant's response, filed 10/16/2006. Claims 1-12 are under consideration.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

2. Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a non-human animal model exhibiting prostate tissue damage characteristic of chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in chronic nonbacterial prostatitis wherein in the animal model is prepared by injection of hydrochloric acid (HCl), wherein the HCl concentration ranges from 0.1 N to 0.4 N, a method of using said nonbacterial prostatitis non-human animal model comprising administering a test substance and determining if it alleviates prostate tissue damage or lower urinary tract disorder symptoms, and a method of making said non-human prostatitis animal model comprising injecting HCl beneath the prostatic capsule wherein the HCl is between 0.1 N and 0.4 N, does not reasonably provide enablement for a nonbacterial prostatitis animal model produced

using any concentration of HCl. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant traverses this rejection on the grounds that Applicants provide specific teachings and examples of how to prepare nonbacterial prostatitis animal models under several different HCl concentrations. One skilled in the art could simply follow the teachings and Examples of the specification to administer different HCl concentrations, and follow the teachings and Examples of the specification to evaluate the resultant effects in order to determine whether or not a particular HCl concentration yielded a suitable nonbacterial prostatitis animal model. The fact that one skilled in the art would have to perform one or more experiments in order to evaluate different HCl concentrations is insufficient to establish a lack of enablement. The fact that not all HCl concentrations may be suitable for establishing a suitable nonbacterial prostatitis animal model is insufficient to establish a lack of enablement. The facts must establish that the experimentation required to practice the full scope of the claims would be undue. No facts supporting such a conclusion are presently of record. Accordingly, the record does not support a holding that it would require undue experimentation to practice the full scope of the claims.

Applicant's arguments are not found persuasive because they do not address the basis of the enablement. The specification and claims providing a specific a nonbacterial prostatitis animal model exhibiting a specific phenotype of a lower UTI disorder characteristically observed in human chronic nonbacterial prostatitis and that is

induced by injecting HCl beneath the prostatic capsule. As stated in the Non-Final rejection, mailed 7/14/2006, the specification teaches that the specific phenotype of the nonbacterial prostatitis animal model varies depending upon concentration of HCl administered (see p. 5). Therefore, also as previously discuss in the non-final rejection (see page 6), a concentration that is higher than the range of HCl taught by the specification will cause extensive tissue damage beyond the claimed phenotype of the animal model, and therefore the animal model will not have the specific phenotype of the claimed nonbacterial prostatitis animal model and therefore not be the same model as claimed. Similarly if a concentration of HCl that is lower than the range disclosed is used, the animal model will also not have the claimed phenotype and therefore not be the same animal as the claim animal model.

So the basis of the rejection was not that it would be undue experimentation for an artisan to make or use non-bacterial prostatitis animal model as Applicant seems to suggest in their arguments is the basis of the rejection, but that the claimed, non-bacterial prostatitis animal model with the claimed phenotype can only be made by administering concentrations within the ranges of 0.1N to 0.4N. Concentrations HCl outside of this range will result in an animal with a different phenotype, not embraced by the claims and not enablement by the specification. Therefore, the specification only enables the animal model previously disclosed in the scope of enablement and the rejection is maintained.

New Matter

3. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 5 recites the range, "4 days to 1 week". However, the specification does not provide literal support for this recitation. This claim originally recited "about 4 days to about 1 week", and the specification makes recitations suggesting that some animal begin to show symptoms of prostatitis around 4 day after the injection and upwards of a week. However, nothing in the specification suggests that the symptoms will arise between the exact range or "4 days to 1 week" as is claimed. Therefore, the specification does not provide figurative support for this recitation as well.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure

from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been amended and no longer reads on the indefinite subject matter. Therefore, the rejection is withdrawn.

Claim 5 was deemed indefinite for the use of the relative term "about" in reference to a measurement. The recitations of about in this claim have been deleted, therefore rendering the rejection moot. Therefore the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record; 2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988).

Applicant traversed this rejection on the grounds that no combination of these teaches would lead one to the presently claim nonbacterial prostatitis model. Applicant argues that Lang et al does not teach a prostatitis model using HCl as claimed but uses DNBS to induce prostatitis. They also claim that Lang et al would teach away from using their methods because the methods of Lang et al result in high fatality rates. They argue that Fulmer, Robinette, and Keetch do not suggest the use of HCl for inducing prostatitis and that these references teach a requirement of specific inflammatory response-inducing agents for developing nonbacterial prostatitis animal

models, which teaches away from the more general inflammatory agent like HCl. They argue that Fulmer teaches the use of LPS, which is a model of bacterial prostatitis not nonbacterial prostatitis as claimed. They also the Robinette induces prostatitis by hormonal induction and Keetch induces prostatitis by injecting homogenates from prostates, which in both cases does not teach the use of HCl. They argue that Royston teaches inflammatory injury induced by HCl in the lung not prostates and therefore is not applicable and they also argue that Goto teaches a model of bacterial prostatitis not nonbacterial prostatitis as claimed because the HCl was administered followed by the administration of *E. Coli* and they also argue that the treatment to the vas deference with HCl only resulted in slight development of prostatitis and therefore is not suitable for a prostatitis model.

These arguments have not been found persuasive for the following reasons.

First, when considering the cited art of a 103 rejection, the different arts are meant to be considered on a whole for their teaching of obviousness of the claimed invention. Therefore, it is not required for each art to teach each limitation of the invention, but rather to demonstrate as a whole that the limitations of the claimed invention would have been made obvious by the art. Therefore, Applicants arguments suggesting that each of the arts do not teach specific embodiments of the invention are not found persuasive.

Second, as previously stated in the Non-Final Rejection, mailed 7/14/2006, Lang et al taught three important concepts: a) nonbacterial prostatitis models were being produced by treating the prostate with non-specific inflammatory agents, such as DNBS

in ethanol that resulted in symptoms commonly known to nonbacterial prostatitis (p. 8 last par), b) other chemical irritants can also be used to produce these non-specific prostate inflammation models as well (p. 9, lines 3-4), and c) because the etiology of abacterial prostatitis is unknown several other non-specific irritant that would induce idiopathic inflammation can and should be used to incite inflammatory responses leading to prostatitis. This last statement of c) also provided motivations to the use of other non-specific inflammatory irritants to produce nonbacterial prostatitis animal models. Applicant's arguments that Lang et al would teach away from using their methods because the methods of Lang et al result in high fatality rates is also not found persuasive because the important information provided by Lang et al is that nonbacterial models were produce even if there were fatalities. Furthermore, Lang et al teaches and even encourages the use of the other irritant in the same method to produce nonbacterial prostatitis to more effectively address the potentially multiple causes of this disorder. Therefore, this art does not teach away from the use of their method, but further encourages the use the method and broaden its uses to other irritants.

Third, since Lang et al suggest using other irritants, Fulmer et al, Robinette et al, and Keetch et al were provided to the general teaching that in fact several other irritants have been used to produce nonbacterial prostatitis in the art. Applicant's arguments that these references teach of requirement of specific inflammatory response-inducing agents for developing nonbacterial prostatitis animal models and therefore teaches away from the more general inflammatory agent like HCl, is not found persuasive

because the claims do not suggest a mechanism by which the irritant must work and again the art was provided to demonstrate that art provides several examples of the use of multiple irritants to make nonbacterial prostatitis models. Applicant's argument that Fulmer teaches the use of LPS, which is a model of bacterial prostatitis not nonbacterial prostatitis as claimed, is technically not correct. It is acknowledged artisan can use LPS as a model for bacterial prostatitis, however LPS is not a bacteria and therefore is does provide a nonbacterial model for prostatitis. Again, the purposes of providing the art of Fulmer was for its general teaching that other irritants are being used to produce nonbacterial prostatitis models as encouraged by Lang et al. Applicants argument that t Robinette induces prostatitis by hormonal induction and Keetch induces prostatitis by injecting homogenates from prostates, which in both cases does not teach the use of HCl, is also not persuasive because again the intention of the art was to demonstrate the multiple irritants are being used in the art to produce nonbacterial prostatitis models as encouraged by Lang et al.

Fourth, Applicant's arguments that Royston et al is not applicable because in a model of nonbacterial lung inflammation is not found persuasive because Royston et al was provided as an art because it generally teaches that HCl was known in the art as a non-specific inflammatory irritant and has been used in the art to provide other nonspecific inflammation models, which also provided motivation to use it with other models for inflammation disorders, such as nonbacterial prostatitis.

Fifth, Applicants arguments that Goto et al teaches a model of bacterial prostatitis not nonbacterial prostatitis as claimed because the HCl was administered

followed by the administration of *E. Coli* and that the treatment to the vas deference with HCl only resulted in slight development of prostatitis and therefore is not suitable for a prostatitis model are not found persuasive because the art was provided to teach that HCl was being used to produce prostatitis models in the art and that the HCl as discussed in applicants arguments does provide for development of prostatitis even if the finding are that it is only slight prostatitis. The claims do not require a degree of prostatitis produced by administering HCl to the prostate. Therefore the fact that the prostatitis is only slight does not have patentable weight because it is not a claim limitation.

Therefore because the Applicant's arguments are not found persuasive the 103 rejection of record is maintained.

6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

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